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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,475	12/05/2003	Steve Pakola	113476.122US1	3082

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EXAMINER

FORD, ALLISON M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,475

Applicant(s)

PAKOLA ET AL.

Examiner

Allison M. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 57-84 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In response to the restriction requirement mailed 8 August 2005 applicants reply, filed 10 February 2006, elected, with traverse, Group I (claims 57-79). The traversal was on the grounds that a search and examination of all claims would not present an undue burden on the examiner. Specifically applicants pointed out that all methods involved the primary step of “contacting the vitreous and/or aqueous humor in the eye of a subject with an effective amount of a composition comprising microplasmin.” Applicants argued that because all claimed methods involved this step, search of all groups would be overlapping and non-burdensome. Applicants also pointed out that the examiner’s characterization of the two groups was inaccurate; specifically, applicants argued that Group I, characterized by the examiner to be “a method of prevention,” was not limited to a method of prevention, but included claims directed to a method of *treating* a vitreoretinal disease or disorder (see claims 66).

In light of applicants’ arguments the restriction requirement has been reconsidered; it has been noted that the previous Group I does contain claims to both a method of treatment and a method of prevention. The following restriction requirement is to replace all previous requirements.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 57-61, 63-72 and 80-84, drawn to a method of treating a vitreoretinal disease or disorder, or a complication thereof, of an eye of a subject having such a disease or disorder, classified in class 604, subclass 521.
- II. Claims 57-65 and 73-84, drawn to a method of preventing a vitreoretinal disease or disorder of an eye of a subject at risk of developing such a disease or disorder, classified in class 424, subclass 94.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct inventions and thus are subject to restriction. The inventions are distinct processes in that the methods are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the two methods are intended for distinct, non-overlapping populations; the method of invention I is directed to subjects having a vitreoretinal disease or disorder, whereas the method of invention II is directed to subjects who do not currently have a vitreoretinal disease or disorder, but are at risk of developing such a disease or disorder. In claims to methods of treating or preventing a disease or disorder by administering a compound or drug (such as microplasmin) it is generally held that the preamble of the claims (i.e. "A method of treating a vitreoretinal disease or disorder" [claim 66] and "A method of preventing a vitreoretinal disease or disorder" [claim 73]) is not merely a statement of effect that may or may not be desired or appreciated, but rather is a statement of the intentional purpose for which the method must be performed. Thus, the methods of inventions I and II are distinct in that they are intended for, and limited to, subjects with different recognized needs; specifically invention I is intended for, and limited to, subjects having a vitreoretinal disease or disorder, and invention II is intended for, and limited to, subjects at risk of developing a vitreoretinal disease or disorder. See *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333-34, 68 USPQ2d, 1154, 1158 (Fed. Cir. 2003). However, applicant is invited to submit on the record that the intended uses, as recited in the preambles, are not to be considered claim limitations, and should not be given patentable weight.

Claim 57 links inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 57. Dependent claims 58-61 and 63-65 are also common to both inventions I and II; however, claims 57-61 and 63-65 will only be considered as they read upon the elected method (i.e. either method of treatment of a vitreoretinal disease or disorder, or a method of preventing a vitreoretinal disease or disorder). Upon the indication of allowability of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims

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depending from or otherwise requiring all the limitations of the allowable linking claim will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

A further election of species is required, as follows:

Claims 58, 67, 74 and 81 are generic to a plurality of disclosed patentably distinct species of microplasmin types, the species of microplasmin types are as follows:

a) recombinant microplasmin; b) stabilized microplasmin; c) stabilized, recombinant microplasmin

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The species are independent or distinct because none of the species are automatically rendered obvious by the others in its group as they are not all art recognized equivalents. Additionally, the disclosure does not connect every species of each of the above described genres by design, structure, operation, or effect. See M.P.E.P. § 806.04(b). A requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner

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if restriction is not required. See M.P.E.P. § 808.01(a). In this case, considering enablement, utility, and description issues for each claimed species, as well as conducting a thorough search of the prior art for each and every combination embodied by the present claims, would pose a serious burden to the examiner.

The examiner wishes to point out for the record that an election of species requirement is for search purposes only and does not necessarily narrow the scope of patentable claims, since all nonelected species are rejoined at the time of allowance. See 37 C.F.R. §1.146 and M.P.E.P. § 809.02(c) for a discussion of species election practice. In short, electing one species does not preclude consideration of the nonelected species later in the prosecution, *i.e.* at the time of allowance. The fact that all of the original claims were generic was the precise reason for the requirement for species election; in the interest of expedient processing of applications, the examiner concentrates on the patentability of the entire invention as it pertains to one species. Once the invention *per se* is claimed in an allowable manner, all disclosed species are rejoined to the claims.

Should applicant traverse on the ground that any of the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

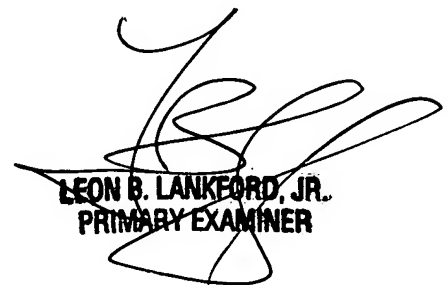
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651



LEON B. LANFORD, JR.
PRIMARY EXAMINER